Remarks

Claims 1 and 3-6 are pending in this application. Claim 2 has been cancelled without prejudice or disclaimer. Claims 1 and 3-6 have been amended.

Claim 1 has been amended to recite "An NAKT-13 cell line or a passage cell line thereof, comprising: a hTERT gene and a SV40T gene each interposed between a pair of LoxP sequences, the cell line being capable of producing insulin and enhancing expression of insulin after excision of the hTERT gene and the SV40T gene." Support for this amendment appears in the specification and claims as originally filed. For example, please *see* page 16, lines 8-13 of the present specification.

Claim 3 has been amended to recite "A human pancreatic islet cell, prepared by a process comprising: excising the hTERT gene and the SV40T gene from the cell line of claim 1." Support for this amendment appears in the specification and claims as originally filed. For example, please *see* page 19, lines 5-18 of the present specification.

Claim 4 has been amended to recite "A method for treating diabetes, comprising: administering an effective amount of the human pancreatic islet cell of claim 3 to a patient in need thereof." Support for this amendment appears in the specification and claims as originally filed. For example, please *see* page 13, lines 13-21 of the present specification.

Claim 5 has been amended to recite "A method for producing insulin, comprising: culturing the NAKT-13 cell line or passage cell line thereof of claim 1 in a culture medium under conditions sufficient to express insulin; and purifying insulin from the culture medium to obtain insulin." Support for this amendment appears in the specification and claims as originally filed. For example, please *see* pages 15 and 16 of the present specification.

Claim 6 has been amended to recite "A method for producing insulin, comprising: culturing the human pancreatic islet cell of claim 3 in a culture medium under conditions sufficient to express insulin; and purifying insulin from the culture medium to obtain insulin." Support for this claim amendment appears throughout the specification and claims as originally filed. For example, please *see* page 15, lines 18-25 of the present specification.

Applicants, by cancelling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims cancelled herein or the original claim scope of any claim amended herein, in a continuing application.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, the Examiner objects to Claim 2 because of the recitation of an address in the claim.

The Examiner asserts that because the depository address could change, incorporation of the address into the claim is improper.

Applicants respectfully submit that, in view of the cancellation of claim 2, this rejection has been rendered moot. Accordingly, the Examiner is respectfully requested to withdraw this objection.

II. At page 2 of the Official Action, claims 5 and 6 have been rejected under 35 USC § 112, second paragraph.

The Examiner asserts that claims 5 and 6 are "incomplete for omitting essential steps, such omission amounting to a gap between the steps." Further, the Examiner asserts that the omitted steps are: "the actual steps taken to express insulin."

Applicants respectfully traverse this rejection.

Applicants submit that amended claims 5 and 6 do not omit any essential steps. Specifically, claim 5 has been amended to recite the steps of culturing the NAKT-13 cell line or passage cell line thereof of claim 1 in a culture medium under conditions sufficient to express insulin, and purifying insulin from the culture medium to obtain insulin. Claim 6 has been amended to recite the steps of culturing the human pancreatic islet cell of claim 3 in a culture medium under conditions sufficient to express insulin and purifying insulin from the culture medium to obtain insulin. Accordingly, Applicants submit that, as amended, claims 5 and 6 both recite the steps taken to express insulin.

In view of the foregoing, it is submitted that claims 5 and 6 are complete within the meaning of 35 USC § 112, second paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At page 3 of the Official Action, claim 2 has been rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner asserts that the specification is not enabling without complete evidence that the NAKT-13 cell line recited in the claims is known and readily available to the public.

In view of the following, this rejection is respectfully traversed.

Applicants respectfully submit that the NAKT-13 cell line has been deposited under the Budapest Treaty. As evidence, Applicants submit herewith a Declaration of Deposit of Microorganism which indicates that the claimed biological material has been deposited under the Budapest Treaty with the International Patent Organism Depository, National Institute of Advanced Industrial Science and Technology under the Accession No. FERM BP-08461 on September 4, 2003; and that the claimed biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

Therefore, it is submitted that the specification enables the full scope of the presently pending claims within the meaning of 35 USC § 112, first paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. At page 5 of the Official Action, claims 1 and 3-6 have been rejected under 35 USC § 102 (b) as being anticipated by de la Tour et al. (Molecular Endocrinology, 2001, 476-483), as evidenced by Halvorsen et al. (Molecular and Cellular Biology, 1999, 19: 1864-1870).

The Examiner asserts that de la Tour et al. teach the reversibly immortalized βlox5 cell line derived according to the method of Halvorsen et al. *See* the Official Action at page 5.

In view of the following, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Amended claim 1 is directed to an NAKT-13 cell line or a passage cell line thereof, comprising: a hTERT gene and a SV40T gene each interposed between a pair of LoxP sequences, the cell line being capable of producing insulin and enhancing expression of insulin after excision of the hTERT gene and the SV40T gene.

Amended claim 3 is directed to a human pancreatic islet cell, prepared by a process comprising: excising the hTERT gene and the SV40T gene from the cell line of claim 1. Claim 6 depends directly from claim 3.

Amended claim 4 is directed to a method for treating diabetes, comprising: administering an effective amount of the human pancreatic islet cell of claim 3 to a patient in need thereof.

Amended claim 5 is directed to a method for producing insulin, comprising: culturing the NAKT-13 cell line or passage cell line thereof of claim 1 in a culture medium under conditions sufficient to express insulin; and purifying insulin from the culture medium to obtain insulin.

In contrast to the presently claimed subject matter, de la Tour et al. is directed to the reversibly immortalized βlox5 cell line. *See* page 477, column 1, first paragraph. However, de la Tour et al. do not teach or suggest an NAKT-13 cell line or a passage cell line thereof, as presently claimed. Specifically, the βlox5 cell line is unrelated to an NAKT-13 cell line or a passage cell line thereof and is not similar to, or an equivalent of, an NAKT-13 cell line or a passage cell line thereof. Therefore, Applicants respectfully submit that the presently claimed subject matter is not anticipated by de la Tour et al. because de la Tour et al. do not teach an NAKT-13 cell line or a passage cell line thereof.

Additionally, Halvorsen et al. also do not teach or suggest an NAKT-13 cell line or a passage cell line thereof. Halvorsen et al. merely describe the introduction of simian virus 40 cell large T antigen (SVLT) into human primary cells. Accordingly, Applicants respectfully submit that the presently claimed subject matter is not anticipated by de la Tour et al. as evidenced by Halvorsen et al. because the cited references do not teach an NAKT-13 cell line or a passage cell line thereof.

In view of the foregoing, Applicants submit that de la Tour et al. as evidenced by Halvorsen et al. do not teach each and every element of the presently claimed subject matter as required for anticipation under 35 USC § 102(b). Thus, the Examiner is respectfully requested to withdraw this rejection as to claims 1 and 3-6.

Conclusion

In view of the foregoing, Applicant submits that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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